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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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07/300,612

04/27/99

LIPPS

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EXAMINER

BASKAR, P

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 12/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/300,612

Applicant(s)

LIPPS ET AL

Examiner

Padma Baskar

Group Art Unit

1645



☒ Responsive to communication(s) filed on Oct 16 and Nov 08, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 5 and 7-16 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 5 and 7-16 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. The request filed on 11/8/00 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/300612 is acceptable and a CPA has been established. An action on the CPA follows.
2. Applicants response to the final office action filed on 10/16/00 has been entered. Claims 1-3 have been canceled. Claims 5 and 7-11 have been amended. Claims 5, 7-16 are pending in the application.

Claim Rejections 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claim 7 is rejected as being vague and indefinite for the recitation of "conducting an ELISA binding or ELISA titer." It is confusing because normally binding of a protein to its ligand is determined by ELISA. Similarly titer of an antigen or antibody is measured by ELISA. Therefore, applicant is advised to amend the claims to clarify the process more clearly.
5. Claim 8 is rejected as being vague and indefinite for the recitation of "food". Food encompasses both liquids and solids. However, applicant has not shown how biological toxin is obtained from food.
6. Claim 8 is rejected as being vague and indefinite for the recitation of "second antibody". What is this antibody? Is it goat anti-mouse IgG or Sheep anti-mouse IgG or what?

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7. Claim 9 is rejected as being vague and indefinite because this method is for assessing neutralizing potency of an antiserum. However there is no step in this method to indicate how that is achieved? There is no bioassay step to indicate neutralization potency.

This method is totally confusing to the examiner because examiner is viewing antiserum against a toxin being an antibody to a toxin. If that is so, toxin is being bound to antiserum and form a complex and also toxin will bind to an antibody made against natural or synthetic peptide and form complex. Therefore it is not clear how these two complexes are being distinguished from each other and how free toxin is being measured? Is lesser the free toxin in the complex and greater the neutralization as measured by ELISA?

8. In view of applicants arguments of record, examiner has withdrawn 35 U.S.C 102 (b) rejections for claims 11-13 and 14-15 as being unpatentable over Lipps et al 1996 (U.S. Patent No. 5,576,297).

9. In view of applicants arguments of record, examiner has withdrawn 35 U.S.C 103 (a) rejections for claims 5, 7-16 as being unpatentable over Lipps et al 1996 (U.S. Patent No. 5,576,297) in view of Harlow and Lane, 1988 (Antibodies: A Laboratory Manual; Chapter 7 and 14).

Claim Rejections - 35 USC 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

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has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

11. Claims 5, 7-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Lipps et al 1998, U.S. Patent 5, 744,449.

Claims are directed to a composition consisting essentially of an antibody made against at least 5-10 amino acids of LTNFs and a process comprising bringing together an anti-LTNF made against LTNFn or against synthetic peptide with one biological toxin to cause an immunological reaction which produces a product which is detected by an ELISA. And also a method for assessing neutralizing potency of an anti-serum against a toxin.

Lipps et al discloses a composition an antibody to LTNFn and LTNFs-10 (i.e. at least 5-10 amino acids of LTNFs) in column 8, lines 9 through 60 and Table VIII. Since these are mouse monoclonals and bind to the toxin by ELISA , it is inherent that these antibodies are IgGs. Furthermore , the prior art discloses a process of bringing together an anti-LTNF made against LTNFn or against synthetic peptide with one biological toxin to cause an immunological reaction which produces a product which is detected by an ELISA (see column 8, lines 61 through column 9 and Table VIII). And also the prior art discloses that the activity of LTNFn resides in the first ten amino acids, or even less (column 9, lines 47-50). Further the prior art also teaches that antibodies versus LTNFn and synthetic with 15 and 10 amino acids reacted more or less similarly with venoms and toxins. Such binding did not occur when non-toxic proteins, such as fetal

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fetal bovine serum or bovine serum were tested indicating that these antibodies are specific for toxins and venoms (LTNF). The toxins show binding affinity to the anti-sera versus LTNFn or LTNFs by ELISA in vitro system, their lethality is neutralized by their antigens when tested in mice in vivo system. Thus the prior art anticipates the claimed invention.

Status of Claims

12. No claims are allowed.

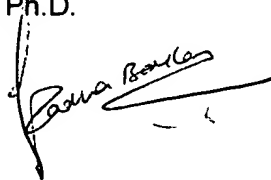
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

12/12/00



RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER